THE COVID-19 PANDEMIC AND ITS EFFECTS ON MEDICATION USAGE

by

Margaret Elizabeth Adamo

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Abstract

Nearly everyone in the world has been affected by the COVID-19 pandemic. Hundreds of thousands of people have died in the U.S. alone, jobs have been lost, family and friends have been separated both physically and emotionally, and the economy has been drastically impacted in a negative way. Research of medication use, specifically H2 receptors, statins, opiates, antidepressant/anti-anxiety and OTC (over the counter) pain medications, during the COVID-19 pandemic determined that COVID-19 has affected an individual's need for certain drugs and that their behaviors and practices contributed to new usage patterns. In addition to a thorough literature review, data from the Gastroparesis Clinical Research Consortium (GpCRC) in the Johns Hopkins School of Public Health data was used to determine a change in medication usage. The data was collected via GpCRC patients' responses to forms and questionnaires regarding their medications and what they are used for, their current mood and mental health, as well as their overall health in general. The same information collected through these forms in 2019, prior to the pandemic, were compared to those that were collected, and are still being collected, during the pandemic. After gathering the data and comparing the pre-COVID and post-COVID numbers, it was determined that medication usage, at this time, has indeed changed during the pandemic. There were some changes and usage did go up in antidepressants/antianxiety and opiate medication usage as as well as over the counter (OTC) pain medication.

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INTRODUCTION

All of humanity has been facing the trials and tribulations that are brought on by pandemics since the first noted epidemic disease (Plague of Athens) in 430 BC (1). Since then, various diseases have emerged (and in some cases have reemerged) throughout history. Within the last century, the world has seen diseases such as Spanish Influenza, Ebola, SARS, and Zika (1).

As of late, the world is now in the midst of the fifth documented pandemic recorded since the flu pandemic of 1918 (2). This disease is COVID-19, the novel human coronavirus. This new pandemic has circled the world, causing a variety of problems while affecting everyone in one way or another. COVID-19 can be traced back to an outbreak of novel human pneumonia cases that were discovered in Wuhan City in China in December, 2019 (2). Early diagnosis suggested that the disease was a viral pneumonia, with symptoms including a dry cough and a fever (2). The virus quickly became a world-wide threat after rapidly spreading to other countries. The World Health Organization (WHO) made the decision that COVID-19 is, in fact, a pandemic on March 11, 2020 (2). It was originally believed that the virus started in the Hunan Seafood and Wildlife Market in Wuhan by way of selling wild animals for human consumption (2). However, being that the first three patients did not have any prior exposure to the market shows that COVID-19 could have had a variety of sources to help the spread in the beginning.

So many changes have taken place throughout the world due to the pandemic, and behavior of all kinds has been affected. Comparing 2019 and 2020 medication use data will determine whether the pandemic has altered the way people are using prescription and non-prescription medication.

REVIEW OF LITERATURE

The effects that COVID-19 have had on the human population world wide are insurmountable. Not only has it been a cause of death worldwide, the disease also has led to job loss, food shortages, social disruption and mental health issues.

COVID-19 deaths

According to the WHO (World Health Organization) dashboard, as of March 27, 2021, globally there has been 2,759,432 confirmed COVID-19 deaths (3), with the United States ranking first (4). It has been shown that the risk of death via COVID-19 falls hardest on the older population (4). For the younger population, 35 years or younger, it has been found that deaths related to COVID-19 such as drug overdoses and suicide surpassed the deaths from the disease itself (4). According to The American Pediatric “Children and COVID-1: State Level Data Report”, as of March 18, 2021, 3.34 million children in the Unites States have tested positive for COVID-19, with a 0.00% - 0.19% mortality rate since the pandemic began (5). This shows that illness due to COVID-19 is not common among children.

Job loss

COVID-19 has also caused massive economic disruption throughout the world. Millions of people have lost access to employment, with economists foretelling a possible global recession that will not only affect the economies of many different counties, but will also allow numerous industries to become vulnerable to a complete shutdown (6). Below is Figure 1 which was

obtained from the Pew Research Center demonstrating the percentage of people whose job has been affected by Coivd-19 (24).

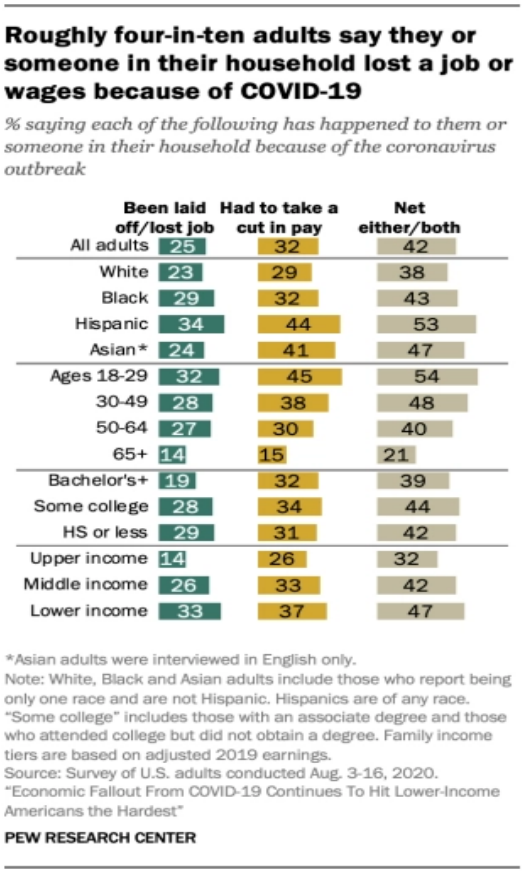

Figure 1

According to a 2021 Statista monthly report, the monthly unemployment rate in the United States in March of 2020, pre-pandemic, was 4.4%, with a sharp rise to 14.7% in April 2020 and finally decreasing to the March 2021 rate of 6% (25).

Financial struggles will more than likely follow job loss, and those who are unfortunate enough to experience wage disruption are over twice as likely as those whose jobs have stayed intact to

say that they have struggled paying their rent or mortgage and other bills and have had to utilized investment money or savings, or borrow money from family and friends (19).

Food Shortage

Globally, COVID-19 has had a large impact on food systems and sources. Factors such as trade restrictions, border closures and confinement measures have been severely affecting the food supply (7). Farmers have been unable to access markets to sell their commodities and agricultural workers are unable to harvest their crops (7). Surveys that have been completed since March of 2020 show food insecurity levels at the highest since the Great Recession (8). Food insecurity occurs when there is no, limited, or uncertain access to ample and nutritious food that is required to live and maintain a healthy lifestyle (8). As with everything that seems to accompany COVID-19, experiencing food insecurity is extremely stressful and leads to various harmful outcomes, both physical and mental, that are short term, and long term as well (8).

Social Distancing

The COVID-19 pandemic has forced most parts of the world to take the necessary steps in stopping the spread of the virus. These steps included social distancing, quarantining, wearing a mask and in some cases, and in the beginning stages, full lockdown. People are social in nature and often depend on others to satisfy their physical needs as well as the overall need to belong (9). Something as mundane as going to work daily was missed when the lockdown went into effect. As mentioned before, prior research shows that the workplace is a major source of both social interaction and a means to form relationships with others (6). Along with the

recommendation of wearing a mask comes the backlash from those who feel as though it is not warranted. There are countless stories on social media about people refusing to wear a mask. These debates often end up with people causing scenes in public places and innocent workers being chastised publicly. Not only have family and friends been separated because of quarantining and social distancing, they are also being separated emotionally as well. There has been concerns conveyed by mental health experts that quarantining and longstanding social distancing will lead to incidences of depression, alcohol abuse, anxiety, and even, in some instances, domestic violence (6).

Medications Affected

Stress brought on by the pandemic may also change medication use in people as stress and anxiety increases and unhealthy, sedentary lifestyles surge. The below groups of medications have been looked at for this analysis due to the likeliness of them being added to a daily regimen if there is a continuous amount of stress.

H2 receptors

The body reacts to stress in different ways, with gastrointestinal function being particularly influenced (16) and the COVID-19 pandemic has surely increased stress levels in people around the world. When someone is faced with a stressful situation, their body automatically reacts in several different ways. One way is to release the hormones epinephrine (which is adrenaline), norepinephrine and cortisol (13). The sudden release of these hormones can cause several health risk factors. For example, the heart must work harder when epinephrine is released, leading to an increase in heart rate, breathing and blood pressure (13). The body will distribute

glucose and fatty acids to use as energy when cortisol is released, which can lead to an increase in appetite and overeating, and an increase in obesity in the stomach area due to fat deposits, as well as having a negative effect on fat in other parts of the body (13). Histamine H2 receptor antagonists and other gastrointestinal medications were looked at for this analysis due to the above mentioned affects stress can potentially have on the gut. According to the National Institute of Health U.S. Laboratory of Medicine, H2 blockers are regularly used for the treatment of common heartburn, gastroesophageal reflux and acid-peptic disease (11). H2 blockers were first approved for use in the United States in 1977, beginning with cimetidine, with ranitidine, famotidine and nizatidine following, in that order, with all four medications eventually being available over-the-counter as well as by prescription. (11) For the most part, H2 receptor blockers are very well tolerated, have mild side-effects if any, and are very commonly used (11).

It has been shown through research that stress can have both short-term and long-term effects on an individual's gastrointestinal tract (15). Research on job stress of professional drivers has shown that stress does have a negative effect on triglycerides, LDL (low density lipoprotein), and HDL (high density lipoprotein) (14). When a person is exposed to stress, brain-gut interactions are compromised, which often leads to the advancement of a large variety of gastrointestinal disorders (15). These illnesses include inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), gastroesophageal reflux disease (GERD), along with other food antigen-related adverse responses, and peptic ulcers (15).

Aside from the aforementioned disorders, other mentionable effects stress has on gut physiology include: 1) an increase in visceral perception; 2) an increase in intestinal

permeability; 3) negative effects on intestinal microbiota; 4) alterations in gastrointestinal mobility; 5) negative effects on regenerative capacity of gastrointestinal mucosa and mucosal blood flow (15).

Statins (anti-hyperlipidemic medications)

Anti-hyperlipidemic medications (statins) are another group of medications that were looked at to see if usage has changed since the start of the pandemic. Statins (HMG-CoA reductase inhibitors) are widely used to treat hypercholesteremia (high cholesterol) (17). Having high cholesterol can increase a person's risk of having a heart attack or a stroke by limiting blood flow. When presented with a stressful situation, an individual could experience hemoconcentration, which is a condition that causes blood to lose fluid, making the cholesterol, and other components, more concentrated (17). Statins have been known to reduce the LDL levels more effectively than other cholesterol-lowering medications that are available, and also have an excellent safety record while being well-tolerated (17). Statins also have positive effects on inflammation, endothelial function, plasma lipoproteins, plaque architecture and stability, and thrombosis (17). As a way to handle stress, people sometimes make poor food choices, often leading towards high fat and sugary "comfort" foods. This in turn could easily cause an unexpected weight gain which could result in higher levels of cholesterol (13). Unhealthy life choices made during stressful times such as abusing alcohol and tobacco and maintaining a sedentary non-active lifestyle would also be components of high cholesterol (13).

Opiates

Opiates (opioids) are very powerful narcotic prescription medications that are used for moderate to severe pain (18). Opioids work by binding to opioid receptors found in the spinal cord, the brain and other areas of the body (18). A few of the most commonly consumed, and often abused opioids are Percocet, Codeine, Oxycodone and Vicodin (18). Unlike the medication groups previously discussed, H2 receptors and statins, opioids do have many different side effects, including the possibility of addiction and dependence on them.

It has been shown through research that people who are exposed to interpersonal trauma or a stressful situation may be susceptible to more chronic pain conditions, therefore leading to the possibility of opioid addiction (19). Possible mechanisms such as stress could easily influence opioid abuse among people with a past, or reoccurring, history of trauma and stress (19). As COVID-19 began forcing shutdowns in March 2020, the deaths from drug overdose have increased by 20% (19), and as of February 16, 2021, 81,003 people had died from drug overdoses, the highest fatal overdose numbers recorded in the U.S. for a single year (19). With the pandemic came isolation, economic difficulties and stress, which are all known to be triggers for addiction, as well as relapses (19). And to make matters worse, the shutdown also has taken away resources that help people achieve and maintain, sobriety (19). COVID-19 has forced various kinds of support groups to either temporarily or permanently close many locations, along with some health care systems having to cut some of their recovery and addiction treatment programs due to the plummeting economy (20).

Antidepressants/antianxiety

Antidepressants' aim is to treat and relieve severe depressive symptoms and prevent them from returning, and the medication is taken so the patient can maintain a normal daily routine after starting to feel emotionally stable (26). Antidepressants are also used to treat other symptoms such as anxiety, restlessness and sleep issues (26). Antidepressants work when taken daily and should be continued throughout the course of depression, leaving many people taking them for several years.

Anxiety disorders have been associated with a high burden of illness while being recognized as the most predominant of psychiatric illnesses (27). Like antidepressants, anxiety medication is prescribed by a physician once the diagnosis has been made. This analysis will determine whether GpCRC patients started an anxiety/antidepressant regimen during the pandemic or maybe had to have their dosage increased to be able to deal with the additional stress that has been brought on.

PROBLEM STATEMENT

Potentially underappreciated when discussing the various aforementioned COVID-19 impacts is whether or not there is a change in medication use during the pandemic. As previously stated, COVID-19 has had some sort of impact on almost everyone world-wide, and another way of determining this would be to compare the medication usage in people pre-COVID and during COVID. Determining, within our data set, whether COVID-19 has affected an individual's needs for drugs and whether their behaviors and practices contributed to the new usage during the pandemic would be beneficial by way of educating health departments and employers so they are aware and can provide the appropriate support, and possibly even public health campaigns, to prevent unnecessary further pain, isolation, suicide, etc.

The added stress of a pandemic may have a definitive effect on what medications, both prescribed and unprescribed, people are taking and how they are taking them.

Throughout the pandemic, routine health care has changed significantly. In the beginning, people were no longer willing to see their physician for routine exams and medication checks for fear of contracting the virus. Also, in some cases, physicians were unable to see their regular patients due to the widespread demand of health care professionals. This could have led to not only patients making their own decisions about their monthly medication, but also patients being left with expired medications or taking higher or lower doses than needed.

As people are continuously fed information about the pandemic through outlets such as the new and social media, they are prone to experience higher levels of stress. This added stress might have negative effects on the outcome of any chronic diseases or previous illness with medication adherence (10). Not only would medication adherence be a problem, but might also

take its toll on patients mentally by leaving them in a hopeless state when it comes to improving their health. The primary objective of this analysis to determine whether COVID-19 has affected an individual's needs for drugs and whether their behaviors and practices contributed to new usage during the pandemic.

RESEARCH METHODOLOGY USED

GpCRC (Gastroparesis Clinical Research Consortium)

In order to determine whether medication use has changed throughout the pandemic, the data that has previously been, and is currently being collected via the Gastroparesis Clinical Research Consortium (GpCRC) within the Department of Epidemiology in the Johns Hopkins Bloomberg School of Public Health will be used to compare various medication usages Pre-COVID (2019) and during COVID (2020 and part of 2021).

The GpCRC is sponsored by the NIDDK (National Institute of Diabetes and Digestive and Kidney Diseases) and focuses on gastroparesis, including the natural history, therapy, and etiology of the disease (23). The consortium's primary objective is to provide an infrastructure that is able to quickly and efficiently conduct clinical trials for medical and surgical interventions to improve treatment for gastroparesis while also performing clinical, epidemiological, and therapeutic research (23). The study follows patients who have gastroparesis by creating a patient registry and tracking their condition and how it changes over time with the understanding that collecting this data may help to gain a better understanding of gastroparesis, allowing for more efficient diagnosis and treatment (23). A total of 300 participants in the ongoing NIH-NIDDK Gastroparesis Research Clinical Consortium (GpCRC) Gastroparesis Registry were included (23). Adult participants were enrolled at six clinical centers throughout the United States, and have gastroparesis or gastroparesis-like symptoms. Institutional Review Boards at each clinical site and the Data Coordinating Center reviewed and approved the study, and participants provided written informed consent (23).

RESEARCH METHODOLOGY TOOLS

The data that was used was collected from the HADS (Hospital Anxiety and Depression Scale) questionnaire (appendix 1), the GpCRC Baseline History form (appendix 2) and the GpCRC Follow-up Medical History form (appendix 3). These forms and questionnaires are completed by participants in the GpCRC study. The information collected on these forms in 2019, prior to the pandemic, were compared to those that were collected, and are still being collected, during the pandemic. The types of medications that were looked at are H2 receptors, Statins/anti-hyperlipidemic, opioids, antianxiety/antidepressants and OTC pain meds.

STATISTICAL METHODS USED

Baseline and follow-up data from phase 3 of the NIH-NIDDK Gastroparesis Clinical Research Consortium Gastroparesis Registry were used in this analysis. Descriptive statistics including means, standard deviations, frequencies, and percentages were used to describe the demographic and clinical characteristics of the population. All screening and follow-up visits between Jan 2019 and April 2021 were utilized, and dates of visits were categorized into quartiles; January - March 2019, April - June 2019, July - September 2019, October - December 2019, January - March 2020, April - June 2020, July - September 2020, October - December 2020, and January - March 2021. Medication use, including H2 receptors, anti-hyperlipidemic, opiates, and antidepressant/anxiety medication and a diagnosis of depression and anxiety, were analyzed as binary 0/1 variables, and the HADS (Hospital Anxiety and Depression Scale), questionnaire, the Gastroparesis Registry 3 Baseline Medical History Form, and the Gastroparesis Registry 3 Follow-up Medical History form were analyzed as continuous scores. Trends in the percentage of medication use over time was examined, both in tabular and graphical form, and p-values were determined using GEE logistic and linear regression analysis, to account for clustering by individual. Also compared were the frequencies of medication use, diagnoses, and scores pre-pandemic (ie, before March 15, 2020) and post-pandemic (on or after March 15, 2020). SAS v. 9.3 and Stata v. 15 were used for the analysis. $P<0.05$ was considered statistically significant.

DATA ANAYSIS

Table 1: Baseline Demographics of Study Population (N=300)	
Participant Characteristics	**N(%)**
Age at enrollment (years)	45.4 (15.6)
Female Gender	258 (86)
Hispanic	66 (22)
Race	
White	264 (89)
Black	27 (9)
Asian	4 (1)
Native Hawaiian	1 (<1)

Table 1 above is a Baseline Demographics of Study Population table. This information was collected at the beginning of the GpCRC study and was used throughout the analysis. The average age of the participant was 45 years and a large population of the participants were white females.

The data below in Table 2, Medications and Medical Diagnosis by Quarter, represents medication use, per quarter (January-March, April-June, July-September, October-December).

TABLE 2 Medications and Medical Diagnosis by Quarter

	2019				2020				2021	
	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Quarter 1	p-value
Medications/Diagnosis										
Medicatons										
H2 Receptors/PPI, N(%)	21 (81)	41 (73)	49 (78)	67 (77)	42 (71)	53 (80)	65 (81)	48 (71)	73 (76)	0.86
Statins/Antihyperlipidemics, N(%)	9 (35)	16 (29)	19 (30)	26 (30)	12 (20)	34 (52)	22 (28)	21 (31)	23 (24)	0.56
Opiates/Pain Medications (prescription), N(%	3 (12)	7 (13)	9 (14)	11 (13)	5 (8)	10 (13)	6 (9)	19 (20)	19 (20)	0.58
Antidepressants/Antianxiety, N(%)	12 (46)	32 (57)	29 (46)	36 (41)	27 (46)	23 (35)	50 (63)	25 (37)	44 (46)	0.54
Pain Medications (over the counter), N(%)	11 (42)	22 (42)	17 (37)	18 (33)	9 (31)	5 (71)	12 (40)	11 (39)	10 (38)	0.97
Diagnosis										
Anxiety	8 (31)	16 (29)	12 (19)	26 (30)	13 (22)	12 (18)	21 (26)	18 (26)	20 (21)	0.37
HADS anxiety, mean (SD)	8.3 (4.3)	9.0 (4.6)	8.3 (5.0)	8.7 (4.9)	8.7 (4.9)	8.4 (4.7)	9.3 (4.3)	8.4 (4.9)	8.9 (5.1)	0.63

The Medications and Medical Diagnosis Pre-COVID and Post-COVID (current) table (Table 3 below) shows the number and percentage of participants who are taking the specific medications as well as the number of those who were diagnosed with anxiety and depression (either by a professional or self-diagnosis).

TABLE 3 Medications and Medical Diagnosis Pre-COVID and Post-COVID (current)

	Pre-COVID N (%)	Present N (%)	p-value
Medications/Diagnosis			
Medicatons			
H2 Receptors/PPI	217 (75)	244 (77%)	0.58
Statins/Antihyperlipidemics	82 (28%)	102 (32%)	0.26
Opiates/Pain Medications (prescription)	41 (14%)	42 (13%)	0.7
Antidepressants/Antianxiety	136 (47%)	143 (45%)	0.54
Pain Medications (over the counter)	77 (37%)	39 (42%)	0.44
Diagnosis			
Anxiety	74 (26%)	73 (23%)	0.41
Depression	80 (28%)	73 (23%)	0.14

The following bar charts (Figure 1 and Figure 2) show the increase in medication use by quarter.

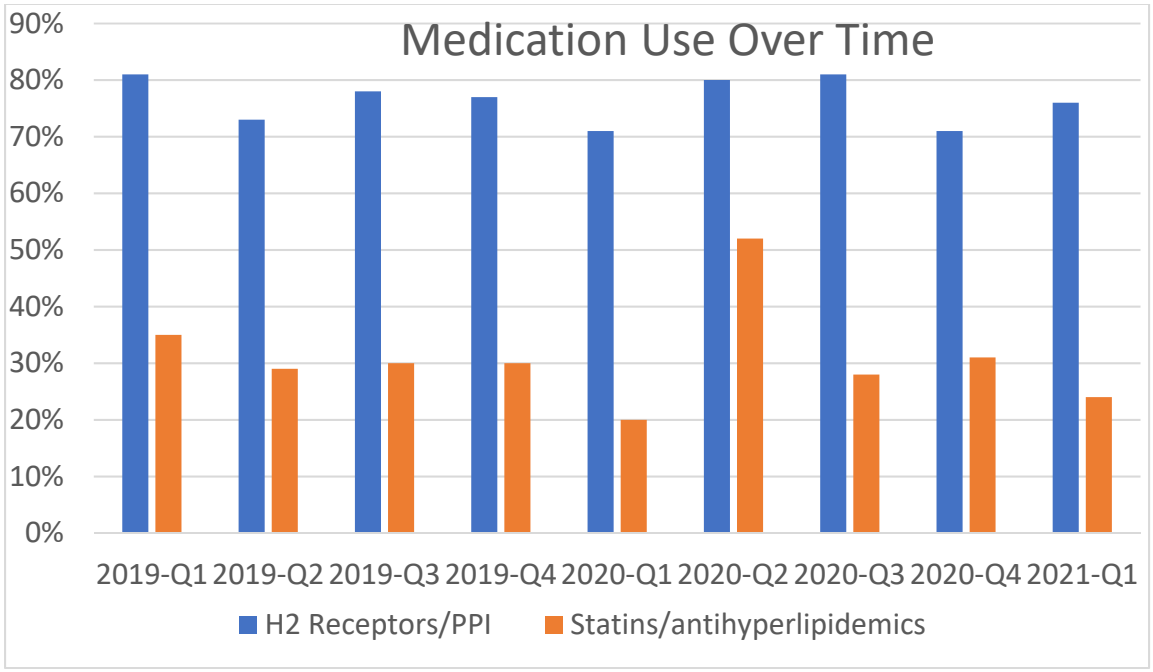

Figure 2

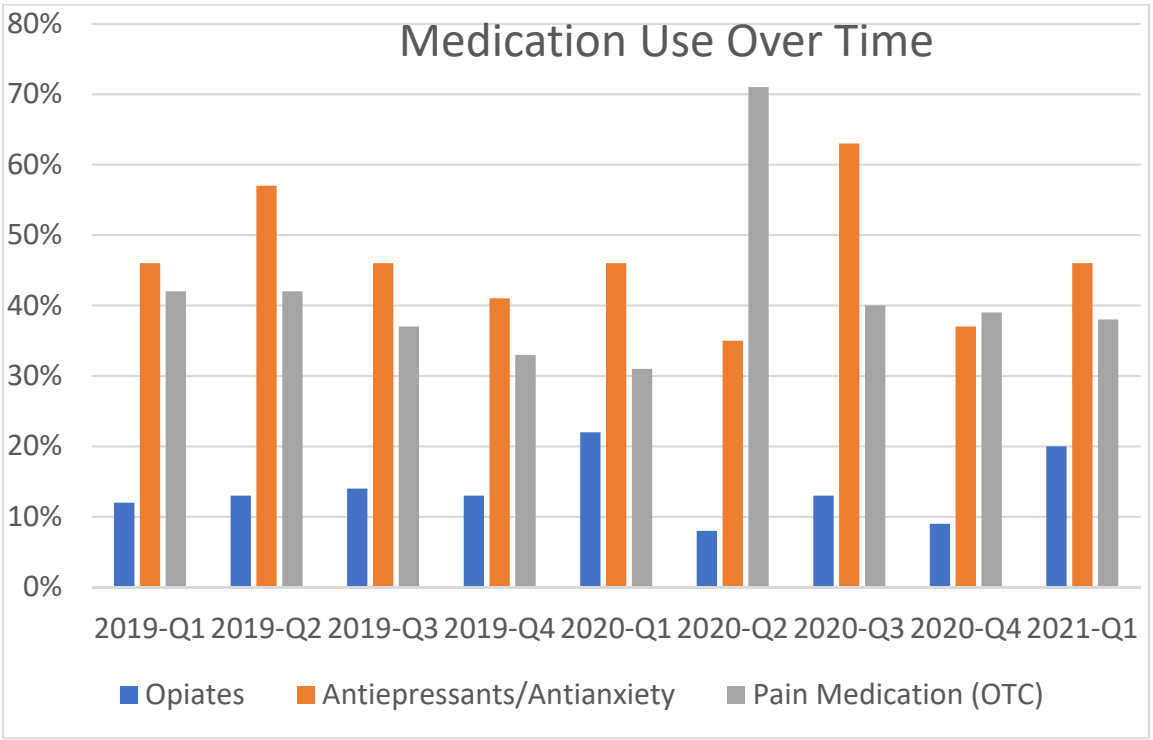

Figure 3

DISCUSSION OF DATA RESULTS

The analysis found that there were no statistically significant changes in any of the medications that were looked at throughout the pandemic. H2 Receptors/PPI medications showed a fluctuation in usage but mostly remained in the 75% to 80% usage range. This shows that at present, the stress of the pandemic does not have that strong of an effect on the participants' blood pressure or the need to start a H2 receptor or other blood pressure medication regimen. Although the literature review does confirm that stress and stressful situations can lead to an increase in blood pressure, the data that was collected did not verify this as there was no statistically significant relationship ($p=0.86$). Like H2 receptors and PPI medications, statin usage both decreased and increased mildly throughout the pandemic. Furthermore, over the counter pain medication usage also showed no signs of a statistically significant increase. Most surprisingly, however, was that there was also no statistically significant change in anti-depression/antianxiety medications throughout the pandemic.

Although differences in medication usage throughout the pandemic were observed when looking at the data, none of the changes were statistically significant (Table 2). And even if, despite the lack of statistical significance, there appeared to be small observed differences in medication usage, since none of the probability levels were statistically significant, the changes could be due to chance as opposed to the pandemic. As mentioned in the limitations, the sample size was smaller than anticipated. Given the potential for chance in the findings, this warrants additional research if a more robust study design can be implemented. While the findings of this analysis were null, the pandemic has entered its second year and the continued

stress of this unprecedented event and the known associations of stress and medication usage highlight the need for increased attention to ensure that we do not have a crisis post-pandemic. The pandemic is still ongoing and there could still be negative repercussions that remain to be seen in regards to medication use and increased decline in mental health.

CONCLUSION/LIMITATIONS

In this study, the original hypothesis of the COVID-19 pandemic affecting certain medication usage did prove to be true. There were changes in medication usage and the increases are significant enough to definitively state that the COVID-19 pandemic changed medication usage. However, given that the sample size is only an N of 300, further investigation into this important public health question could easily be done at a later date with hopefully a much larger cohort. Unfortunately, although there have been major improvements and completed milestones, the pandemic is not over. Meaning that it is not too late to continue with studies dealing with medication use as we enter the second year of the pandemic. Just because the changes in medication usage were not significantly seen during the first year, there are sure to be some changes in usage before the pandemic is over. The pandemic is undoubtedly causing stress and emotion distress to almost everyone, and as previously stated, stress has both physical and mental negative effect on a person including elevated blood pressure, higher cholesterol due to gut issues, depression and anxiety.

The research that was conducted had some limitations that are worth mentioning. There was no prosepective questionnaire to give to the patients to see if there were any other conditions that could have been associated with COVID-19 that they would have otherwise personally reported. Another limitation was the sample size. Due to COVID-19 restrictions, our sample size was not as large as we would have liked. Clinics that saw the patients had restrictions in place for in-person visits, and even when the clinics were cleared to once again see patients, some were fearful and did not want to keep, or make their appointments. Also, based on the

first year of pandemic, and now that we are in the second, we could be missing a good portion of the population by doing this one year in already. Furthermore, this is a cohort of patients with gastroparesis and may not represent the general U.S. population.

Also, if the forms had listed allergy and asthma medication usage that could have been looked at to determine whether quarantine affected those with either seasonal or indoor allergies and asthma. Often combined, allergies and asthma, although are both upper respiratory problems, are different conditions entirely. When someone has allergies, it is actually their immune system responding to an allergen in the environment such as dust, mold, pet dander, and pollen (21). Asthma, is somewhat of an immune system response to allergens as well, but has additional triggers such as air temperature, strenuous exercises, and strong odors (21). When an asthma attack occurs, the lungs become inflamed, constricting the muscles around the airways, resulting in shortness of breath, wheezing, and chest tightness (21).

Looking at allergy and asthma medication usage before and during the pandemic could show that quarantining may have changed people's daily exposer to various allergy and asthma triggers. Perhaps being at home for long periods of time increased exposure to pet dander, mold and possibly even dust mites?

Additional studies that can be done to further investigate this area would be to look at people that were negatively associated with the upticks of medication usage. Did they receive one of the available COVID vaccines? Are they making any additional poor health choices due to stress?

Further research could include a possible follow-up with the same patient charts in the next year to see if medication use increased or normalized. Also, as mentioned previously, a study to

determine whether or not allergy medicine increased during the quarantine could lead to the discovery of new allergens and asthma triggers.

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Appendices

Appendix A:	Hospital Anxiety and Depression Scale (HADS)©
Appendix B:	Gastroparesis Registry 3 Baseline History Form (Confidential – not for sharing or citation)
Appendix C:	Gastroparesis Registry 3 Follow-up Medical History Form (Confidential – not for sharing or citation)

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:

Total score: Depression (D) _____ Anxiety (A) _____

0-7 = Normal

8-10 = Borderline abnormal (borderline case)

11-21 = Abnormal (case)

Gastroparesis Registry 3

BH - Baseline Medical History

Purpose: To collect baseline history information about the patient to screen for potential enrollment into the Gastroparesis Registry 3.

When: Screening visit s.

Administered by: Clinical Coordinator, reviewed by Study Physician.

Respondent: Patient.

Instructions: Collect information by interview and/or chart review. Enter "**m**" if the patient does not know the answer to a query. If a ⚠C is checked for any item, further review is necessary by the study physician who will determine whether the diagnosis or condition in the ⚠C item renders the patient ineligible for or unlikely to comply with the requirements of the GpR 3 study. If a STOP or EMg is checked for any item, the patient is ineligible and cannot enroll in the Gastroparesis Registry 3 unless the item can be resolved within the 112 day screening window. The BH form cannot be keyed to the data system if there is a STOP or EMg item present. The form should be retained in a study file for further evaluation as appropriate.

A. Center, visit, and patient identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date *(date this form is initiated):*

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit code: s ____ ____ ____

6. Form & revision: b h 1

7. Study: GpR 3 7

B. Gastroparesis history

8. Has the patient had symptoms of gastroparesis of at least 12 weeks duration *(do not have to be contiguous)* with varying degrees of nausea, vomiting, early satiety, or post-prandial fullness:

Yes (1) No (2)
STOP

These next 6 questions ask about the period in the past when your gastroparesis symptoms started

9. Date symptoms of gastroparesis or functional dyspepsia started:

____ ____ – ____ ____ ____ – ____ ____
day mon year

10. Which best describes the onset of gastroparesis or functional dyspepsia symptoms *(check only one):*

Acute start (1)
Insidious or gradual (2)
Other *(specify)* (3)

_____
specify

11. Did the patient have an initial infectious prodrome with resultant chronic gastroparesis symptoms:

Yes (1) No (2)
13.

12. Specify infectious symptoms *(check only one):*

Upper respiratory flu-like illness *(fever, cough, body aches):* (1)
Food-poisoning like symptoms *(nausea, vomiting after eating bad food):* (2)
Gastroenteritis *(nausea, vomiting, diarrhea):* (3)
Other *(specify):* (4)

_____
specify

13. What prompted the evaluation for gastroparesis *(check all that apply)*

a. Nausea: (1)
b. Vomiting: (1)
c. Bloating: (1)
d. Early satiety *(a sense that your stomach is full after eating only a small amount of food):* (1)
e. Postprandial fullness *(a sense of fullness after the meal):* (1)
f. Abdominal pain: (1)
g. Diarrhea: (1)
h. Constipation: (1)
i. Anorexia *(loss of appetite):* (1)
j. Weight loss: (1)
k. Weight gain: (1)
l. Gastroesophageal reflux symptoms such as heartburn: (1)
m. Problems with the management of diabetes or glycemic control: (1)
n. Other *(specify):* (1)

_____
specify

14. Select the **one predominant symptom** listed in item 13 (a through n) that prompted the evaluation for gastroparesis: _____ a-n
These next 3 questions ask about your current symptoms of gastroparesis.

15. Which best describes the patient's current nature of gastroparesis symptoms *(check only one):*

Chronic symptoms, but stable severity of symptoms (1)
Chronic symptoms, but progressive worsening of symptoms (2)
Chronic symptoms, but with some improvement over time (3)
Chronic symptoms with periodic exacerbations with worsening of symptoms (4)
Cyclic pattern of exacerbations with periods of feeling well in between (5)
Asymptomatic (6)
Other *(specify):* (7)

_____
specify

16. Which best describes the current gastroparesis severity *(check only one):*

(Grade 1) Mild gastroparesis: *Symptoms mild to moderate and relatively controlled. Able to maintain weight and nutrition on a regular diet.* (1)
(Grade 2) Compensated gastroparesis: *Moderate symptoms with only partial control with use of daily medications. Able to maintain nutrition with dietary adjustments.* (2)
(Grade 3) Gastroparesis with gastric failure: *Refractory symptoms that are not controlled, ER visits, frequent doctor visits or hospitalizations and/or inability to maintain nutrition via oral route.* (3)
Other *(specify):* (4)

_____
specify

17. What is the investigator's assessment of the patient's current symptoms of gastroparesis:

None (0)
Very mild (1)
Mild (2)
Moderate (3)
Severe (4)
Very severe (5)

18. What is the present understanding of the primary etiology of the patient's gastroparesis

a. Diabetes: (1) → **20.**
b. Post fundoplication: (1) → **19.**
c. Idiopathic: (1) → **20.**
d. Other *(specify):* (1) → Elig

_____
specify

19. Which form of fundoplication was used *(check all that apply)*

a. Nissen: (1)
b. Dor: (1)
c. Toupet: (1)
d. Other *(specify)* (1)

Elig

specify

C. Family history

20. Have members of the patient's family been diagnosed with gastroparesis:

Yes (1) No (2)

23.

21. Which family members *(check all that apply)*

a. Brother: (1)
b. Sister: (1)
c. Mother: (1)
d. Father: (1)
e. Son: (1)
f. Daughter: (1)
g. Spouse/partner: (1)
h. Other *(specify)* (1)

specify

22. Which family members with gastroparesis also have diabetes *(check all that apply)*

a. Brother: (1)
b. Sister: (1)
c. Mother: (1)
d. Father: (1)
e. Son: (1)
f. Daughter: (1)
g. Spouse/partner: (1)
h. Other *(specify)* (1)

specify

D. Weight history

23. What is the patient's current weight *(patient's report):*

____ ____ ____ lbs

24. What was the patient's approximate weight when diagnosed with gastroparesis or functional dyspepsia *(date in item 9):*

____ ____ ____ lbs

25. How does the patient's current weight compare to prior to the start of his/her gastroparesis or functional dyspepsia symptoms:

Increased (1)
26a.
Decreased (2)
26b.
Same (3)
27.

26. Weight compared to start of gastroparesis

a. How much more does the patient weigh now compared to the start of his/her gastroparesis:

____ ____ ____ lbs

27.

b. How much less does the patient weigh now compared to the start of his/her gastroparesis:

____ ____ ____ lbs

27. Weight prior to gastroparesis

a. What is the most the participant has ever weighed prior to the gastroparesis diagnosis:

____ ____ ____ lbs

b. At what age did the patient weigh the most:

____ ____ age in years

28. What is the least the patient has ever weighed since age 18, but prior to the start of gastroparesis or functional dyspepsia symptoms:

____ ____ ____ lbs

29. At what age did the patient weigh the least since age 18, but prior to the gastroparesis symptoms:

____ ____ age in years

30. Over the last six months, has the patient gained weight, lost weight, or stayed the same:

- Gained weight (1)
- Lost weight (2)
- Stayed the same (3)

31. What was the patient's approximate weight six months ago:

____ ____ ____
lbs

32. *Review flashcard #7* Which (picture) best describes your weight pattern over the past 5 years *(check only one):*

- Up and down, up and down (1)
- Up gradually (2)
- Up sharply (gained a lot in a brief interval) (3)
- Down gradually (4)
- Down sharply (lost a lot in a brief interval) (5)
- No or minimal change (6)

E. Tobacco cigarette smoking history *(interview with patient; not by chart review)*

33. Have you ever smoked tobacco cigarettes:

- No, never (1) → **38.**
- Yes, in the past but not anymore (2)
- Yes, currently smoke cigarettes (3)

34. Did you smoke cigarettes regularly *("No" means less than 20 packs of cigarettes in a lifetime or less than 1 cigarette a day for one year):*

Yes (1) No (2) → **38.**

35. How old were you when you first started regular cigarette smoking:

____ ____
years

36. How old were you when you (last) stopped smoking cigarettes *(code as "n" if the patient did not stop smoking):*

____ ____
years

37. On the average of the entire time that you smoked cigarettes, how many cigarettes did you smoke per day:

____ ____ ____
cigarettes/day

F. Alcohol consumption (AUDIT-C) history *(interview with patient; not from chart review)*

38. How often have you had a drink containing alcohol in the past year (including beer and wine) *(check only one):*

- Never (0) → **41.**
- Monthly or less (1)
- Two to four times a month (2)
- Two to three times a week (3)
- Four or more times a week (4)

39. How many drinks containing alcohol do you have on a typical day when you are drinking *(check only one):*

- 1 or 2 (0)
- 3 or 4 (1)
- 5 or 6 (2)
- 7 to 9 (3)
- 10 or more (4)

40. How often have you had six or more alcoholic drinks on one occasion in the past year (including beer and wine) *(check only one):*

- Never (0)
- Less than monthly (1)
- Monthly (2)
- Weekly (3)
- Daily or almost daily (4)

G. Menstrual history

41. Is the patient female:

Yes (1) No (2) → **46.**

42. Characterize the menstrual history in the past year *(check only one):*

- Regular periods (1)
- Irregular periods (2)
- Rare periods (3)
- No periods (4) → **44.**

43. Are gastroparesis symptoms worse around the time of menstruation:

Yes (1) No (2)

46.

If yes, check all symptoms that are worse around the time of menstruation (menstrual periods):

a. Nausea: (1)
b. Vomiting: (1)
c. Bloating: (1)
d. Early satiety: (1)
e. Postprandial fullness: (1)
f. Abdominal pain: (1)
g. Diarrhea: (1)
h. Constipation: (1)
i. Anorexia: (1)
j. Weight loss: (1)
k. Weight gain: (1)
l. Gastroesophageal reflux symptoms: (1)
m. Problems with management of diabetes or glycemic control: (1)
n. Other *(specify):* (1)

_____
specify

44. Is patient postmenopausal *(natural or surgical):*

Yes (1) No (2)

46.

45. What was the patient's age at menopause:

____ ____
age in years

H. Medical history

(⚠C means CAUTION; Flags conditions that are exclusionary; verify with Study Physician)

46. Has the patient ever been diagnosed with diabetes *(NOT including gestational diabetes):*

Yes (1) No (2)

54.

47. Diabetes type:

Type 1: (1)
Type 2: (2)
Unknown: (3)
Other: (4)

48. Age when diagnosed with diabetes: ____ ____
age in years

49. Weight when diagnosed with diabetes: ____ ____ ____
lbs

50. Has the patient been diagnosed with any complications of diabetes:

Yes (1) No (2)

54.

If yes, check all that apply:

a. Retinopathy (eye changes from diabetes): (1)
b. Nephropathy (kidney disease from diabetes): (1)
c. Peripheral neuropathy (numbness and/or tingling in distal legs and feet from diabetes): (1)

51. Has the patient had laser treatment for diabetic retinopathy:

Yes (1) No (2)

52. Has the patient had prior episodes of diabetic ketoacidosis (ketones present in the blood requiring hospitalization):

Yes (1) No (2)

53. Describe the patient's glucose control in the past 6 months (interview with patient) *(check all that apply)*

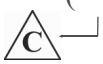
a. Well controlled: (1)
b. Hypoglycemic events (symptomatic and/or requiring intervention): (1)
c. Glucose levels above 300 mg/dL: (1)
d. Postprandial high glucose levels: (1)
e. Postprandial low glucose levels: (1)

54. Has the patient ever been diagnosed with or treated for any of the following *(check all that apply; source of information can be interview and/or chart review):*

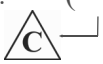
a. Gestational diabetes *(diabetes of pregnancy):* (1)

b. Pyloric obstruction: (1)

c. Intestinal obstruction: (1)

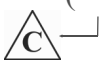


d. Inflammatory bowel disease (IBD): (1)

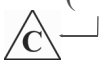


e. Irritable bowel syndrome (IBS): (1)

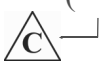
f. Eosinophilic gastroenteritis: (1)



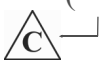
g. Acute renal failure: (1)



h. Acute liver failure: (1)



i. Advanced liver disease *(Child's B or C; a CPT score of 7 or greater):* (1)



j. Hepatitis B: (1)

k. Hepatitis C: (1)

l. Peptic ulcer disease: (1)

m. GERD: Gastroesophageal reflux disease: (1)

n. Celiac disease: (1)

o. Small intestinal bacterial overgrowth (SIBO): (1)

p. Colonic inertia: (1)

q. Interstitial cystitis: (1)

r. Bladder dysfunction: (1)

s. Diverticulosis: (1)

t. Endometriosis: (1)

u. Blood clots: (1)

v. Hemophilia *(bleeding disorder):* (1)

w. Rheumatoid arthritis: (1)

x. Scleroderma: (1)

y. Systemic lupus erythematosus (lupus or SLE): (1)

z. Collagen vascular disease: (1)

aa. Raynaud's phenomenon: (1)

ab. Other unidentified systemic autoimmune disorder: (1)

ac. Thyroid disease *(hormonal abnormality):* (1)

ad. Malignancy *(cancer):* (1)

ae. Peripheral neuropathy *(non-diabetic numbness or tingling in hands or legs) (see 50c for diabetic neuropathy):* (1)

af. Migraine headaches: (1)

ag. Chronic headaches ≥ 15 per month (other than migraines): (1)

ah. Seizure disorder or epilepsy: (1)

ai. Chronic fatigue syndrome: (1)

aj. Postural orthostatic tachycardia syndrome (POTS): (1)

ak. Hypertension: (1)

al. Heart attack, myocardial infarction: (1)

am. Coronary artery disease: (1)

an. Cerebrovascular disease: (1)

ao. Stroke, cerebrovascular accident (CVA): (1)

ap. Hyperlipidemia *(high cholesterol, high triglycerides):* (1)

aq. Chronic pancreatitis: (1)

ar. Episode(s) of acute pancreatitis: (1)

as. How many episodes of acute pancreatitis has the patient ever had: ____ 1-9

at. Cholelithiasis *(gallstones):* (1)

au. Gallbladder disease without gallstones including chronic cholecystitis, gallbladder dyskinesia: (1)

av. Gout: (1)

aw. Polycystic ovary syndrome (PCOS): (1)

ax. Dermatologic disorders: (1)

ay. Myopathy: (1)

az. Autonomic nervous system dysfunction: (1)

ba. Fibromyalgia: (1)

bb. Multiple sclerosis: (1)

bc. Parkinson's disease: (1)

bd. ALS: Amyotrophic lateral sclerosis: (1)

be. Anorexia: (1)

bf. Bulemia: (1)

bg. Binge eating: (1)

bh. Avoidant/ Restrictive eating disorder (ARFID): (1)

bi. Non-specific eating disorders: (1)

bj. Posttraumatic Stress Disorder (PTSD): (1)

bk. Major (clinical) depression requiring treatment: (1)

bl. Schizophrenia: (1)

bm. Bipolar disorder: (1)

bn. Obsessive compulsive disorder: (1)

bo. Severe anxiety disorder requiring treatment: (1)

bp. Personality disorder requiring treatment: (1)

bq. Dyslexia or learning problems including ADHD (attention deficit hyperactivity disorder): (1)

br. Primary neurologic conditions that could cause nausea and/or vomiting such as increased intracranial pressure, space occupying or inflammatory/infectious lesions: (1)

bs. Chronic renal failure and/or hemodialysis or peritoneal dialysis: (1)

bt. None of the above: (1)

55. Has the patient ever had any abdominal and/or pelvic surgical procedures:

Yes (1) No (2)

68.

56. Has the patient ever had a total gastric resection:

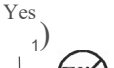
Yes (1) No (2)

57. Has the patient ever had a gastroduodenostomy, gastrojejunostomy, esophagogastrostomy or gastric bypass:

Yes (1) No (2)

58. Has the patient ever had a subtotal gastric resection (vagotomy, pyloroplasty, antrectomy):

Yes (1) No (2)

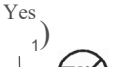


59. Has the patient ever had surgical or endoscopic pyloroplasty or pyloromyotomy (G-POEM or POP):

Yes (1) No (2)

60. Has the patient ever had a esophagectomy:

Yes (1) No (2)



61. Has the patient ever had stapling or banding of the stomach:

Yes (1) No (2)

62. Has the patient ever had a Nissen, Dor, or Toupe fundoplication for GERD:

Yes (1) No (2)

63.

a. Date:

____ ____–____ ____ ____–____ ____
day mon year

b. Did current gastroparesis symptoms start before or after fundoplication for GERD:

Before (1)

After (2)

63. Has the patient ever had any other fundoplication (not Nissen, Dor or Toupe):

Yes (1) No (2)

64. Has the patient ever had a cholecystectomy (gallbladder removal):

Yes (1) No (2)

65.

a. Date:

____ ____–____ ____ ____–____ ____
day mon year

b. Were there gallstones in the gallbladder:

Yes (1) No (2)

c. Did the patient's symptoms that led to the gallbladder removal improve after removal of the gallbladder:

Yes (1) No (2)

d. Did current gastroparesis symptoms start before or after the removal of the gallbladder:

Before (1)
After (2)

65. Has the patient had an appendectomy:

Yes (1) No (2)

66.

a. Date:

____ ____–____ ____ ____–____ ____
day mon year

b. Did current gastroparesis symptoms start before or after the appendectomy:

Before (1)
After (2)

66. Has the patient had a hysterectomy:

Yes (1) No (2)

67.

a. Date:

____ ____–____ ____ ____–____ ____
day mon year

b. Did current gastroparesis symptoms start before or after the hysterectomy:

Before (1)
After (2)

67. Has the patient had a Caesarean section:

Yes (1) No (2)

68.

a. Date:

____ ____–____ ____ ____–____ ____
day mon year

b. Did current gastroparesis symptoms start before or after the C-section:

Before (1)
After (2)

68. Has the patient visited the Emergency Department for gastroparesis in the past year:

Yes (1) No (2)

70.

69. How many times did the patient visit the Emergency Department for gastroparesis in the past year:

____ ____ ____

70. Has the patient been hospitalized for gastroparesis symptoms in the past year:

Yes (1) No (2)

73.

71. How many times was the patient hospitalized for gastroparesis in the past year:

____ ____ ____

72. Reason(s) for hospitalization *(check all that apply):*

a. Nausea: (1)
b. Vomiting: (1)
c. Abdominal pain: (1)
d. Dehydration: (1)
e. Hyperglycemia: (1)
f. Hypoglycemia: (1)
g. GI bleed: (1)
h. Other *(specify):* (1)

_____
specify

I. Nutrition and Gastric Electrical Stimulator (GES) use

73. Has the patient ever had a formal nutrition consult at any time after the onset of gastroparesis:

Yes (1) No (2)

74. On most days during the last 6 months, did the patient follow a gastroparesis diet: small, more frequent meals, low fat, low fiber meals:

Yes (1) No (2)

75. Has the patient received total parenteral nutrition (TPN) in the past year:

Yes (1) No (2)

76. What is the patient's current source of nutrition *(check all that apply):*

a. Oral feeding: (1)
b. Enteral feeding: (1)
c. Parenteral feeding: (1)

77. Does the patient have a G tube:

Yes (1) No (2)
79.

a. G tube has been in place since:

____ ____ ____–____ ____
month year

78. What does the patient use this G tube for *(check all that apply):*

a. Nutrition: (1)
b. Hydration: (1)
c. Medication: (1)
d. Decompression: (1)
e. Other *(specify):* (1)

_____
specify

79. Does the patient have a J tube:

Yes (1) No (2)
81.

a. J tube has been in place since:

____ ____ ____–____ ____
month year

80. What does the patient use this J tube for *(check all that apply):*

a. Nutrition: (1)
b. Hydration: (1)
c. Medication: (1)
d. Decompression: (1)
e. Other *(specify):* (1)

_____
specify

81. Does the patient have a central line/PICC:

Yes (1) No (2)
83.

a. Central line/PICC has been in place since:

____ ____ ____–____ ____
month year

82. What does the patient use this central line/PICC for *(check all that apply):*

a. Nutrition: (1)
b. Hydration: (1)
c. Medication: (1)
d. Other *(specify):* (1)

_____
specify

83. Does the patient have a gastric electrical stimulator (GES):

Yes (1) No (2)
84.

a. Gastric electrical stimulator (GES) has been in place since:

____ ____ ____–____ ____
month year

b. In the patient's opinion, has the gastric electrical stimulator (GES) improved his/her gastroparesis symptoms:

Yes (1) No (2)

c. Is the gastric electrical stimulator (GES) currently turned on:

Yes (1) No (2)
84.

d. Specify reason why it is turned off:

_____
specify

J. Medication use

84. Has the patient used insulin for diabetes in the past 6 months:

Yes (1) No (2)

86.

(If yes, check all that apply):

a. Insulin glulisine (Apidra): (1)

b. Insulin lispro (Humalog): (1)

c. Insulin aspart (Novolog): (1)

d. Insulin glargine (Lantus): (1)

e. Insulin detemir (Levemir): (1)

f. Insulin isophane (Humulin N, Novolin N): (1)

85. Has the patient used an insulin pump in the past 6 months:

Yes (1) No (2)

86.

a. Is the patient currently using an insulin pump:

Yes (1) No (2)

86. Has the patient used any other antidiabetic medications in the past 6 months:

Yes (1) No (2)

87.

(If yes, check all that apply):

a. Biguanide: Metformin (Glucophage) (1)

b. Thiazolidinediones: Pioglitazone (Actos), Rosiglitazone (Avandia) (1)

c. Sulfonylureas (first gen): Chlorpropamide (Diabinese),Tolazamide (Tolinase), Tolbutamide (Orinase) (1)

d. Sulfonylureas (second gen): Glyburide (Micronase, DiaBeta, Glynase), Glimepiride (Amaryl):, Glipizide (Glucotrol) (1)

e. Meglitinides: Repaglinide (Prandin), nateglinide (Starlix) (1)

f. Alpha-glucosidase inhibitors: miglitol (Glycet), acarbose (Precose) (1)

g. Injectable GLP analogs and agonists: Exenatide (Byetta, Bydureon), Liraglutide (Victoza), Lixisenatide (Lyxumia), Semaglutide (Ozempic) (1)

h. Dipeptidyl peptidase-4 (DPP-4) inhibitors: Alogliptin (Nesina), Sitagliptin (Januvia), Saxagliptin (Onglyza), linagliptin (Tradjenta) (1)

i. SGLT-2 inhibitors: Canagliflozin (Invokana), Empagliflozin (Jardiance), Dapagliflozin (Farxiga) (1)

j. Rosiglitazone Maleate/Glimepiride (Avandaryl) (1)

k. Pramlintide (Symlin) (1)

l. Other *(specify):* (1)

_____

specify

87. Has the patient taken any anti-hyperlipidemic medications in the past 6 months:

Yes (1) No (2)

88.

(If yes or unsure, check all that apply):

a. HMG-COA reductase inhibitors (Atorvastatin [Lipitor], Simvastatin [Zocor], Rosuvastatin [Crestor], Fluvastatin sodium [Lescol], Lovastatin [Mevacor], Pravastatin sodium [Pravachol]):, (1)

b. Bile acid sequestrant (Colestipol hydrochloride [Colestid]): (1)

c. Fibric acid (Gemfibrozil [Lopid], Fenofibrate [Tricor]): (1)

d. Nicotinic acid (Niaspan): (1)

e. Other *(specify):* (1)

_____
specify

88. Has the patient taken any anticoagulant/antiplatelet medications in the past 6 months:

Yes (1) No (2)

89.

(If yes or unsure, check all that apply):

a. Apixaban (Eliquis): (1)

b. Clopidogrel (Plavix): (1)

c. Dabigatran (Pradaxa): (1)

d. Dipyridamole (Persantine, Aggrenox): (1)

e. Enoxaparin (Lovenox): (1)

f. Heparin: (1)

g. Rivaroxaban (Xarelto): (1)

h. Ticlopide (Ticlid): (1)

i. Warfarin (Coumadin): (1)

j. Other *(specify):* (1)

_____
specify

k. Other *(specify):* (1)

_____
specify

89. Has the patient taken any systemic corticosteroids in the past 6 months:

Yes (1) No (2)

90.

(If yes or unsure, check all that apply):

a. Betamethasone sodium (Celestone): (1)

b. Cortisol: (1)

c. Cortisone: (1)

d. Dexamethasone (Decadron): (1)

e. Hydrocortisone (Hydrocortone): (1)

f. Methylprednisolone (Solu-Medrol): (1)

g. Prednisolone (Prelone): (1)

h. Prednisone: (1)

i. Triamcinolone (Acetocot, Amcort, Aristocort, Kenacort): (1)

j. Other *(specify):* (1)

_____
specify

k. Other *(specify):* (1)

_____
specify

90. Has the patient taken any cardiovascular/antihypertensive medications in the past 6 months:

Yes (1) No (2) → **91.**

(If yes or unsure, check all that apply):

a. Class III antiarrhythmic agent (Amiodarone [Pacerone]): (1)

b. Dihydropyridine calcium channel blocker (Amlodipine besylate [Norvasc], Felodipine [Plendil], Nifedipine [Adalat, Procardia]): (1)

c. Beta$_1$-adrenergic blocker (Atenolol [Tenormin], Metoprolol [Lopressor]: (1)

d. Non-selective beta blocker (Carvedilol [Coreg], Propranolol [Inderal], Timolol maleate [Blocadren]): (1)

e. Angiotensin-converting-enzyme inhibitors (Benazepril [Lotensin], Captopril [Capoten], Enalapril [Vasotec], Lisinopril [Prinivil, Zestril], Ramipril [Altace], Quinapril [Accupril]): (1)

f. Alpha-2 adrenergic agonist (Clonidine [Catapres]): (1)

g. Digoxin (Lanoxin): (1)

h. Diltiazem (Cardizem): (1)

i. Alpha-1 adrenergic blocker (Doxazosin [Cardura], Terazosin [Hytrin]): (1)

j. Furosemide (Lasix): (1)

k. Hydrochlorothiazide (Esidrix, HydroDIURIL): (1)

l. Hydrochlorothiazide + triamterene (Dyazide): (1)

m. Angiotensin II receptor antagonist (Losartan potassium [Cozaar], Valsartan [Diovan], Candesartan [Atacand]): (1)

n. Losartan potassium with hydrochlorothiazide (Hyzaar): (1)

o. Verapamil (Calan): (1)

p. Other *(specify):* (1)

_____
specify

q. Other *(specify):* (1)

_____
specify

91. Has the patient taken any estrogen, progestin, hormone replacement therapy, or selective estrogen receptor modulators in the past 6 months:

Yes (1) No (2) → **92.**

(If yes or unsure, check all that apply):

a. Conjugated estrogen (Premarin/Prempro): (1)

b. Diethylstilbestrol and methyltestosterone (Tylosterone): (1)

c. Esterified estrogen (Estratab, Menest): (1)

d. Estradiol (Estrace): (1)

e. Ethinyl estradiol (Estinyl): (1)

f. Androgens (Fluoxymesterone [Android-F, Halotestin], Methyltestosterone [Android], Nandrolone [Deca-Durabolin, Hybolin Decanoate, Kabolin]): (1)

g. Progestins (Norethindrone [Micronor], Progesterone [Prometrium], Norgestrel [Ovrette], Levonorgestrel [Norplant], Medroxyprogesterone [Cycrin, Provera], Megestrol [Megace]): (1)

h. Combination oral contraceptives (Alesse, Demulen, Desogen, Estrostep, Genora, Intercon, Levlen, Levlite, Levora, Loestrin, Lo-Ovral, Necon, Nelova, Nordette, Norethin, Norinyl, Ortho Cyclen, Ortho-Novum, Ortho Tri-Cyclen, Ovral, Tri-Levlen, Triphasil, Trivora, Zovia): (1)

i. Synthetic anabolic steroids (Oxandrolone [Oxandrin], Oxymetholone [Anadrol]): (1)

j. Selective estrogen receptor modulator (Raloxifene [Evista], Tamoxifen [Nolvadex]): (1)

k. Other *(specify):* (1)

_____
specify

l. Other *(specify):* (1)

_____
specify

K. Medication use for gastroparesis symptoms

For items 92-93: Have the patient use flashcard #8 to indicate the duration of use and perceived benefit for gastroparesis symptoms for each medication he/she uses/used

92. Is the patient currently taking any proton pump inhibitors, histamine H2 receptor antagonists or other similar medications:

Yes (1) No (2)

93.

(If yes, answer all that apply using flashcard #8):

	Duration (1-5)	Benefit (0-5)
a. Esomeprazole (Nexium):	____	____
b. Omeprazole (Prilosec, Zegerid):	____	____
c. Lansoprazole (Prevacid):	____	____
d. Pantoprazole (Protonix):	____	____
e. Rabeprazole (Aciphex):	____	____
f. Dexlansoprazole (Dexilant):	____	____
g. Ranitidine (Zantac):	____	____
h. Famotidine (Pepcid):	____	____
i. Nizatidine (Axid):	____	____
j. Cimetidine (Tagamet):	____	____
k. Antacids, *(specify):*	____	____

_____
specify

l. Other *(specify):*	____	____

_____
specify

m. Other *(specify):*	____	____

_____
specify

93. Is the patient currently taking any prokinetic medications :

Yes (1) No (2)

94.

(If yes, answer all that apply using flashcard #8):

	Duration (1-5)	Benefit (0-5)
a. Azithromycin (Zithromax):	____	____
b. Bethanechol (Duvoid, Urecholine):	____	____
c. Clarithromycin (Biaxin):	____	____
d. Domperidone (Motilium):	____	____
e. Erythromycin:	____	____
f. Metoclopramide (Reglan):	____	____
g. Prucalopride (Resolor) (see also 97l):	____	____
h. Tegaserod (Zelnorm):	____	____
i. Cisapride (Propulcid):	____	____
j. Other *(specify):*	____	____

_____
specify

k. Other *(specify):*	____	____

_____
specify

94. Has the patient ever had Botox injected into pylorus for his/her gastroparesis symptoms:

Yes (1) No (2)

96.

a. Perceived benefit: ____ 0-5

95. Has the patient had botulinum toxin (Botox) injected into pylorus for his/her gastroparesis symptoms in the last 3 months:

Yes (1) No (2)

96.

a. Perceived benefit: ____ 0-5

96. Is the patient currently using any of the following medications:

Yes (1) No (2)

97.

(If yes, answer all that apply using flashcard #8):

	Duration (1-5)	Benefit (0-5)
a. Prochlorperazine (Compazine):	____	____
b. Promethazine (Pentazine, Phenergan):	____	____
c. Trimethobenzamide (Benzacot, Stemetic, Tigan):	____	____
d. Meclizine (Antivert):	____	____
e. Serotonin (5-HT3) antagonists (Ondansetron [Zofran], Tropisetron [Navoban], Granisetron [Kytril, Sancuso Patch], Palonosetron [Aloxi], Dolasetron [Anzemet]):	____	____
f. Neurokinin-1 receptor antagonists (Aprepitant [Emend]):	____	____
g. Tricyclic antidepressants (Amitriptyline [Elavil], Desipramine [Norpramin], Nortriptyline [Aventyl, Pamelor]):	____	____
h. Dronabinol (Marinol):	____	____
i. Tetracylcic antidepressants (Mirtazapine [Remeron]):	____	____
j. Bupropion (Wellbutrin):	____	____
k. Selective Serotonin Reuptake Inhibitors (SSRI)[Citalopram (Celexa), Escitalopram (Lexapro), Fluoxetine (Prozac), Paroxetine (Paxil), Sertraline (Zoloft)]:	____	____
l. Venlafaxine (Effexor):	____	____
m. Anxiolytic (Buspirone [BuSpar]):	____	____
n. Chlordiazepoxide (Librax):	____	____
o. Benzodiazepines (Lorazepam [Ativan], Alprazolam [Xanax], Diazepam [Valium], Oxazepam [Serax], Clonazepam [Klonopin], Temazepam [Restoril, Temaz], Flurazepam):	____	____
p. Meprobamate (Equanil, Meprospan):	____	____
q. Quetiapine fumarate (Seroquel):	____	____
r. Dicyclomine (Bentyl):	____	____
s. Olanzapine (Zyprexa):	____	____
t. Tetrahydrocannabinol (Syndros):	____	____
u. Other *(specify):*	____	____

_____
specify

v. Other *(specify):*	____	____

_____
specify

97. Is the patient currently using any of the following medications for constipation:

Yes (1) No (2)

98.

(If yes, answer all that apply using flashcard #8):

	Benefit (0-5)
a. Bisacodyl (Dulcolax):	____
b. Colchicine (Colcrys):	____
c. Docusate sodium (Colace):	____
d. Fiber supplements:	____
e. Lactulose:	____
f. Linaclotide (Linzess):	____
g. Lubiprostone (Amitiza):	____
h. Methylnaltrexone (Relistor):	____
i. Misoprostol (Cytotec):	____
j. Plecanatide (Trulance):	____
k. Polyethylene glycol (Miralax):	____
l. Prucalopride (Resolor):	____
m. Naloxegol (Movantik):	____
n. Senna (Senokot):	____
o. Magnesium oxide:	____
p. Other *(specify):*	____

_____
specify

98. Is the patient currently taking any pain relieving, analgesics, non-steroidal anti-inflammatory, or aspirin containing medications (non-narcotic) either regular usage or as needed basis (prn):

Yes (1) No (2)

99.

(If yes, answer all that apply using flashcard #8):

	Benefit (0-5)
a. Acetaminophen (Tylenol):	____
b. Aspirin - 325 mg:	____
c. Celecoxib (Celebrex):	____
d. Ibuprofen (Advil, Motrin):	____
e. Indomethacin (Indocin):	____
f. Naproxen (Aleve, Naprosyn):	____
g. Ketorolac (Toradol):	____
h. Other *(specify):*	____

_____
specify

i. Other *(specify):*	____

_____
specify

j. Other *(specify):*	____

_____
specify

99. Is the patient currently taking any narcotic pain medications:

Yes (1) No (2)

101.

(If yes, answer all that apply using flashcard #8):

	Duration (1-5)	Benefit (0-5)
a. Acetaminophen (30 mg)/ codeine phosphate (Tylenol #3):	____	____
b. Acetaminophen (60 mg)/ codeine phosphate (Tylenol #4):	____	____
c. Acetaminophen/hydrocodone bitartrate (Lortab, Norco, Vicodin):	____	____
d. Acetaminophen/oxycodone hydrochloride (Percocet, Tylox):	____	____
e. Aspirin/oxycodone hydrochloride (Percodan):	____	____
f. Butalbital/acetaminophen/ caffeine (Esgic - Plus):	____	____
g. Fentanyl transdermal (Duragesic patch):	____	____
h. Fentanyl oral (Fentora, Actiq):	____	____
i. Hydromorphone hydrochloride (Dilaudid):	____	____
j. Oxycodone hydrochloride (OxyContin):	____	____
k. Methadone hydrochloride:	____	____
l. Morphine sulfate:	____	____
m. Pentazocine (Talacen):	____	____
n. Tapentadol (Nucynta):	____	____
o. Tramadol hydrochloride/acetaminophen (Ultram, Ultracet):	____	____
p. Other *(specify):*	____	____

_____
specify

100. Is the patient taking the narcotic pain medication for *(check all that apply)*

a. Pain related to his/her gastroparesis symptoms, including abdominal pain: (1)

b. Headache pain: (1)

c. Leg pain: (1)

d. Back pain: (1)

e. Other pain *(specify):* (1)

_____
specify

101. Has the patient taken any of the following neuropathic pain medications in the past 6 months:

Yes (1) No (2)

102.

(If yes, answer all that apply using flashcard #8):

	Duration (1-5)	Benefit (0-5)
a. Duloxetine (Cymbalta):	____	____
b. Gabapentin (Neurontin):	____	____
c. Pregabalin (Lyrica):	____	____
d. Divalproex sodium (Depakote):	____	____
e. Topiramate (Topamax):	____	____
f. Other *(specify):*	____	____

_____
specify

L. Alternative therapies for gastroparesis symptoms

For items 102-103: Have the patient use flashcard #8 to indicate the duration of use and perceived benefit for each alternative therapy they have used for gastroparesis symptoms.

102. Has the patient ever used alternative medicine or complementary medicine products or procedures for treatment of his/her symptoms related to gastroparesis *(e.g., bloating, nausea, vomiting, abdominal pain):*

Yes (1) No (2)

103.

	Duration (1-5)	Benefit (0-5)
a. Probiotics:	____	____

_____
specify

_____
specify

b. Herbal supplements:	____	____

_____
specify

_____
specify

_____
specify

c. Acupuncture:	____	____
d. Acupressure bands/bracelets *(ie, Relief band):*	____	____
e. Reflexology:	____	____
f. Hypnotherapy:	____	____
g. Therapeutic Massage:	____	____
h. Ginger:	____	____
i. Iberogast:	____	____
j. Other *(specify):*	____	____

_____
specify

103. Does the patient use a cannabis product such as marijuana, THC (tetrahydrocannabinol), CBD (cannabidiol):

Yes (1) No (2)

→ **106.**

(If yes, use flashcard #8 to answer items 103 a and b):

a. Duration of use *(1-5):* ____

b. Perceived benefit *(0-5):* ____

c. How often do you use these cannabis products:

Rarely (less than once per month)	(1)
About once per month	(2)
About once per week	(3)
Several times a month	(4)
Several times per week	(5)
About once per day	(6)
More than once per day	(7)

104. Which cannabis products do you use: *(check all that apply)*

a. Marijuana (medical use):	(1)
b. Marijuana (non-medical/recreational use):	(1)
c. THC:	(1)
d. CBD:	(1)
e. Marinol (Dronabinol) (see also 96h):	(1)
f. Nabilone (Cesamet):	(1)
g. Tetrahydrocannabinol (Syndros) (see also 96t):	(1)

105. For which reason(s) do you use these cannabis products: *(check all that apply)*

a. Recreational:	(1)
b. Reduce nausea:	(1)
c. Reduce abdominal pain:	(1)
d. Improve appetite:	(1)
e. Other *(specify):*	(1)

_____
specify

M. Administrative information

106. Study Physician PIN: ____ ____ ____

107. Study Physician signature:

_____

108. Clinical Coordinator PIN: ____ ____ ____

109. Clinical Coordinator signature:

_____

110. Date form reviewed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

Flash Card #7	Which pattern best describes your weight pattern over the past 5 years?	
1		**Up and down, up and down**
2		**Up gradually**
3		**Up sharply (gained a lot in a brief interval)**
4		**Down gradually**
5		**Down sharply (lost a lot in a brief interval)**
6		**No or minimal change**

Flash Card #8	Which BEST DESCRIBES the DURATION of use for the medication you took or are taking?
1	Less than 1 month
2	1-6 months
3	6-11 months
4	1-2 years
5	More than 2 years

Flash Card #8	Which BEST DESCRIBES the BENEFIT you received from the medication you took or are taking for your gastroparesis symptoms?
0	Not taking for gastroparesis symptoms
1	No or minimal benefit for gastroparesis symptoms
2	Better
3	Much better
4	Worse
5	Much worse

Gastroparesis Registry 3

FH - Follow-up Medical History

Purpose: To collect follow-up medical information about the patient.
When: f024, f048, f072, f096, f120, f144.
Administered by: Clinical Coordinator, reviewed by the Study Physician.
Respondent: Patient.
Instructions: Collect information by interview and/or chart review.

A. Center, visit, and patient identification

1. Center ID: ____ ____ ____ ____

2. Patient ID: ____ ____ ____ ____

3. Patient code: ____ ____ ____

4. Visit date *(date this form is initiated):*

____ ____–____ ____ ____–____ ____
day mon year

5. Visit code: f ____ ____ ____

6. Form & revision: f h 1

7. Study: GpR 3 7

B. Interval identification

8. Date of last Follow-up Medical History form *(if this is f024, record date of Baseline History form):*

____ ____–____ ____ ____–____ ____
day mon year

C. Gastroparesis evaluation

9. Has the patient had an upper endoscopy since the date in item 8:

Yes (*1) No (2)

**Complete the EG form.*

10. Has the patient had a gastric emptying scintigraphy since the date in item 8:

Yes (*1) No (2)

**Complete the GE form.*

11. Since the date in item 8, which best describes the patient's symptoms of gastroparesis *(check all that apply):*

a. Nausea: (1)
b. Vomiting: (1)
c. Bloating: (1)
d. Early satiety *(a sense that your stomach is full after eating only a small amount of food):* (1)
e. Postprandial fullness *(a sense of fullness after the meal):* (1)
f. Abdominal pain: (1)
g. Diarrhea: (1)
h. Constipation: (1)
i. Anorexia *(loss of appetite):* (1)
j. Weight loss: (1)
k. Weight gain: (1)
l. Gastroesophageal reflux symptoms such as heartburn: (1)
m. Problems with the management of diabetes or glycemic control: (1)
n. Other *(specify):* (1)

_____
specify

o. No symptoms related to gastroparesis: (1)

13.

12. Select the predominant symptom listed in item 11 (a through n): ____

13. Since the date in item 8, has the patient experienced a significant improvement in his/her gastroparesis symptoms:

Yes (1) No (2)

14. Since the date in item 8, has the patient experienced any exacerbation(s) of his/her gastroparesis symptoms:

Yes (1) No (2)

17.

a. Number of Emergency room visits due to gastroparesis symptoms:

____ ____

15. Since the date in item 8, has the patient been admitted to the hospital for gastroparesis:

Yes (1) No (2)

17.

a. Since the date in item 8, how many times has the patient been admitted to the hospital for gastroparesis: ____ ____

16. Reason(s) for hospitalization *(check all that apply):*

a. Intractable nausea and vomiting: (1)

b. Abdominal pain: (1)

c. Dehydration: (1)

d. Hyperglycemia: (1)

e. GI bleed: (1)

f. Other *(specify):* (1)

_____
specify

17. Since the date in item 8, which best describes the nature of the patient's gastroparesis symptoms *(check only one):*

Chronic symptoms, but stable severity of symptoms (1)

Chronic symptoms, but progressive worsening of symptoms (2)

Chronic symptoms, but with some improvement over time (3)

Chronic symptoms with periodic exacerbations with worsening of symptoms (4)

Cyclic pattern of exacerbations with periods of feeling well in between (5)

Asymptomatic (6)

Other *(specify):* (7)

_____
specify

18. Since the date in item 8, which best describes the patient's gastroparesis severity *(check only one):*

(Grade 1) Mild gastroparesis: *Symptoms mild to moderate and relatively controlled. Able to maintain weight and nutrition on a regular diet.* (1)

(Grade 2) Compensated gastroparesis: *Moderate symptoms with only partial control with use of daily medications. Able to maintain nutrition with dietary adjustments.* (2)

(Grade 3) Gastroparesis with gastric failure: *Refractory symptoms that are not controlled. Having ER visits, frequent doctor visits or hospitalizations and/or inability to maintain nutrition via oral route.* (3)

Other *(specify):* (4)

_____
specify

D. Tobacco cigarette smoking history
(interview with patient)

19. Since the date in item 8, have you smoked cigarettes regularly *("No" means less than 1 cigarette a day per week on average):*

Yes (1) No (2)

22.

20. On average, how many days per week have you smoked cigarettes:

____
days

21. On the days that you smoked, about how many cigarettes did you smoke per day:

____ ____ ____
cigarettes/day

E. Alcohol consumption (AUDIT-C) since the date in item 8 *(interview with patient)*

22. Since the date in item 8, how often have you had a drink containing alcohol (including beer and wine) *(check only one):*

Never	(0)
	25.
Monthly or less	(1)
Two to four times a month	(2)
Two to three times a week	(3)
Four or more times a week	(4)

23. Since the date in item 8, how many drinks of alcohol, beer, or wine have you had on a typical day when you are drinking *(check only one):*

1 or 2	(0)
3 or 4	(1)
5 or 6	(2)
7 to 9	(3)
10 or more	(4)

24. Since the date in item 8, how often have you had six or more drinks of alcohol, beer, or wine on one occasion *(check only one):*

Never	(0)
Less than monthly	(1)
Monthly	(2)
Weekly	(3)
Daily or almost daily	(4)

F. Menstrual history

25. Is the patient female: Yes (1) No (2)

32.

26. Characterize the menstrual history since the date in item 8 *(check only one):*

Regular periods	(1)
Irregular periods	(2)
Rare periods	(3)
No periods	(4)

28.

27. Are gastroparesis symptoms worse around the time of menstruation (menstrual periods): Yes (1) No (2)

32.

If yes, check all symptoms that are worse around the time of menstruation:

a. Nausea:	(1)
b. Vomiting:	(1)
c. Bloating:	(1)
d. Early satiety:	(1)
e. Postprandial fullness:	(1)
f. Abdominal pain:	(1)
g. Diarrhea:	(1)
h. Constipation:	(1)
i. Anorexia:	(1)
j. Weight loss:	(1)
k. Weight gain:	(1)
l. Gastroesophageal reflux symptoms:	(1)
m. Problems with management of diabetes or glycemic control:	(1)
n. Other *(specify):*	(1)

_____
specify

28. Has the patient been pregnant since the date in item 8: Yes (1) No (2)

29.

a. If yes, what is the status of the pregnancy:

Still pregnant	(1)
Delivery of child	(2)
Miscarriage	(3)
Abortion	(4)

29. Since the date in item 8, did the patient have a hysterectomy: Yes (1) No (2)

30. Is the patient postmenopausal *(surgical or natural):* Yes (1) No (2)

32.

31. Since the date in item 8, has the patient entered natural menopause: Yes (1) No (2)

G. Medical history

32. Is the patient diabetic: Yes (1) No (2) → **35.**

a. Is this diagnosis of diabetes new since the date in item 8: Yes (1) No (2)

33. Describe the patient's glucose control since the date in item 8 *(interview with patient; check all that apply):*

a. Well controlled (1)

b. Hypoglycemic events *(symptomatic and/or requiring intervention)* (1)

c. Glucose levels above 300 mg/dL: (1)

d. Episodes of diabetic ketoacidosis: (1)

e. Postprandial high glucose levels (1)

f. Postprandial low glucose levels (1)

34. Since the date in item 8, has the patient been diagnosed with or treated for any of the following complications of diabetes:

Yes (1) No (2) → **35.**

If yes, check all that apply:

a. Retinopathy (eye changes from diabetes): (1)

b. Nephropathy (kidney disease from diabetes): (1)

c. Peripheral neuropathy (numbess and/or tingling in distal legs and feet from diabetes): (1)

35. Since the date in item 8, has the patient been diagnosed with or treated for any of the following *(check all that apply; source of information can be interview and/or chart review):*

a. Gestational diabetes *(diabetes of pregnancy):* (1)

b. Pyloric obstruction: (1)

c. Intestinal obstruction: (1)

d. Inflammatory bowel disease (IBD): (1)

e. Irritable bowel syndrom (IBS): (1)

f. Eosinophilic gastroenteritis: (1)

g. Acute renal failure: (1)

h. Acute liver failure: (1)

i. Advanced liver disease *(Child's B or C; a CPT score of 7 or greater):* (1)

j. Hepatitis B: (1)

k. Hepatitis C: (1)

l. Peptic ulcer disease: (1)

m. GERD: Gastroesophageal reflux disease: (1)

n. Celiac disease: (1)

o. Small intestinal bacterial overgrowth (SIBO): (1)

p. Colonic inertia: (1)

q. Interstitial cystitis: (1)

r. Bladder dysfunction: (1)

s. Diverticulosis: (1)

t. Endometriosis: (1)

u. Blood clots: (1)

v. Hemophilia *(bleeding disorder):* (1)

w. Rheumatoid arthritis: (1)

x. Scleroderma: (1)

y. Systemic lupus erythematosus (lupus or SLE): (1)

z. Collagen vascular disease: (1)

aa. Raynaud's phenomenon: (1)

ab. Other unidentified systemic autoimmune disorder: (1)

ac. Thyroid disease *(hormonal abnormality):* (1)

ad. Malignancy *(cancer):* (1)

ae. Peripheral neuropathy (**non-diabetic** numbess or tingling in hands or legs) (see 34c for diabetic neuropathy): (1)

af. Migraine headaches: (1)

ag. Chronic headaches ≥ 15 per month (other than migraines): (1)

ah. Seizure disorder or epilepsy: (1)
ai. Chronic fatigue syndrome: (1)
aj. Postural orthostatic tachycardia syndrome (POTS): (1)
ak. Hypertension: (1)
al. Heart attack, myocardial infarction: (1)
am. Coronary artery disease: (1)
an. Cerebrovascular disease: (1)
ao. Stroke, cerebrovascular accident (CVA): (1)
ap. Hyperlipidemia *(high cholesterol, high triglycerides):* (1)
aq. Chronic pancreatitis: (1)
ar. Episode(s) of acute pancreatitis: (1)
as. Cholelithiasis (gallstones): (1)
at. Gallbladder disease without gallstones including chronic cholecystitis, gallbladder dyskinesia: (1)
au. Gout: (1)
av. Polycystic ovary syndrome (PCOS): (1)
aw. Dermatologic disorders: (1)
ax. Myopathy: (1)
ay. Autonomic nervous system dysfunction: (1)
az. Fibromyalgia: (1)
ba. Multiple sclerosis: (1)
bb. Parkinson's disease: (1)
bc. ALS: Amyotrophic lateral sclerosis: (1)
bd. Anorexia: (1)
be. Bulemia: (1)
bf. Binge eating: (1)
bg. Avoidant/ Restrictive eating disorder (ARFID): (1)
bh. Non-specific eating disorders: (1)
bi. Major (clinical) depression: (1)
bj. Schizophrenia: (1)
bk. Bipolar disorder: (1)
bl. Obsessive compulsive disorder: (1)
bm. Severe anxiety disorder: (1)
bn. Personality disorder: (1)
bo. Post-traumatic Stress Disorder (PTSD): (1)
bp. Dyslexia or learning problems including ADHD (attention deficit hyperactivity disorder): (1)
bq. Other *(specify):* (1)

_____
specify

br. None of the above: (1)

36. Since the date in item 8, has the patient had any abdominal/pelvic surgical procedures:

Yes (1) No (2)

37. ___

(Check all that apply):

a. Total gastric resection: (1)
b. Subtotal gastric resection *(vagotomy, antrectomy):* (1)
c. Stapling or banding of the stomach: (1)
d. Gastrojejunostomy: (1)
e. Fundoplication for GERD: (1)
f. Cholecystectomy *(gall bladder removal):* (1)
g. Gastrostomy *(surgical or endoscopic):* (1)
h. Jejunostomy: (1)
i. Appendectomy: (1)
j. Hysterectomy: (1)
k. Surgical pyloroplasty or pyloromyotomy: (1)
l. Endoscopic pyloromyotomy (G-POEM or POP): (1)
m. Peroral endoscopic myotomy (POEM) for esophageal motility disorder: (1)
n. Gastroduodenostomy: (1)
o. Other GI procedure *(specify):* (1)

_____
specify

H. Nutrition and gastric electrical stimulator (GES) use

37. What is the patient's current source of nutrition *(check all that apply):*

a. Oral feeding: (1)
b. Enteral feeding: (1)
c. Parenteral feeding: (1)

38. Since the date in item 8, has the patient had a formal nutrition consult:

Yes (1) No (2)

39. Since the date in item 8, has the patient received total parenteral nutrition (TPN):

Yes (1) No (2)

40. Since the date in item 8, has the patient had any of the following placed:

	Yes	No
a. G tube:	(1)	(2)
b. J tube:	(1)	(2)
c. Central line/PICC:	(1)	(2)
d. Gastric electrical stimulator:	(1)	(2)

41. Is a gastric electrical stimulator present:

Yes (1) No (2) → **42.**

a. Is gastric electrical stimulator currently turned on:

Yes (1) No (2)

42. Since the date in item 8, has the patient had any of the following removed:

	Yes	No
a. G tube:	(1)	(2)
b. J tube:	(1)	(2)
c. Central line/PICC:	(1)	(2)
d. Gastric stimulator:	(1)	(2)

I. Medication use

43. Since the date in item 8, has the patient used insulin for diabetes:

Yes (1) No (2) → **44.**

(If yes, check all that apply):

a. Insulin glulisine (Apidra): (1)
b. Insulin lispro (Humalog): (1)
c. Insulin aspart (Novolog): (1)
d. Insulin glargine (Lantus): (1)
e. Insulin detemir (Levemir): (1)
f. Insulin isophane (Humulin N, Novolin N): (1)

44. Since the date in item 8, has the patient used an insulin pump:

Yes (1) No (2)

a. Is the patient currently using an insulin pump:

Yes (1) No (2)

45. Since the date in item 8, has the patient used any other antidiabetic medications:

Yes (1) No (2)

46.

(If yes, check all that apply):

a. Biguanide: Metformin (Glucophage) (1)

b. Thiazolidinediones: Pioglitazone (Actos), Rosiglitazone (Avandia) (1)

c. Sulfonylureas (first gen): Chlorpropamide (Diabinese),Tolazamide (Tolinase), Tolbutamide (Orinase) (1)

d. Sulfonylureas (second gen): Glyburide (Micronase, DiaBeta, Glynase), Glimepiride (Amaryl):, Glipizide (Glucotrol) (1)

e. Meglitinides: Repaglinide (Prandin), nateglinide (Starlix) (1)

f. Alpha-glucosidase inhibitors: miglitol (Glycet), acarbose (Precose) (1)

g. Injectable GLP analogs and agonists: Exenatide (Byetta, Bydureon), Liraglutide (Victoza), Lixisenatide (Lyxumia), Semaglutide (Ozempic) (1)

h. Dipeptidyl peptidase-4 (DPP-4) inhibitors: Alogliptin (Nesina), Sitagliptin (Januvia), Saxagliptin (Onglyza), linagliptin (Tradjenta) (1)

i. SGLT-2 inhibitors: Canagliflozin (Invokana), Empagliflozin (Jardiance), Dapagliflozin (Farxiga) (1)

j. Rosiglitazone Maleate/Glimepiride (Avandaryl) (1)

k. Pramlintide (Symlin) (1)

l. Other *(specify):* (1)

specify

46. Since the date in item 8, has the patient taken any anti-hyperlipidemic medications:

Yes (1) No (2)

47.

(If yes or unsure, check all that apply):

a. HMG-COA reductase inhibitors (Atorvastatin [Lipitor], Simvastatin [Zocor], Rosuvastatin [Crestor], Fluvastatin sodium [Lescol], Lovastatin [Mevacor], Pravastatin sodium [Pravachol]):, (1)

b. Bile acid sequestrant (Colestipol hydrochloride [Colestid]: (1)

c. Fibric acid (Gemfibrozil [Lopid], Fenofibrate [Tricor]): (1)

d. Nicotinic acid (Niaspan): (1)

e. Other *(specify):* (1)

specify

47. Since the date in item 8, has the patient taken any anticoagulant/antiplatelet medications:

Yes (1) No (2)

48.

(If yes or unsure, check all that apply):

a. Apixaban (Eliquis): (1)

b. Clopidogrel (Plavix): (1)

c. Dabigatran (Pradaxa): (1)

d. Dipyridamole (Persantine, Aggrenox): (1)

e. Enoxaparin (Lovenox): (1)

f. Heparin: (1)

g. Rivaroxaban (Xarelto): (1)

h. Ticlopide (Ticlid): (1)

i. Warfarin (Coumadin): (1)

j. Other *(specify):* (1)

specify

k. Other *(specify):* (1)

specify

48. Since the date in item 8, has the patient taken any systemic corticosteroids:

Yes (1) No (2)

49.

(If yes or unsure, check all that apply):

a. Betamethasone sodium (Celestone): (1)

b. Cortisol: (1)

c. Cortisone: (1)

d. Dexamethasone (Decadron): (1)

e. Hydrocortisone (Hydrocortone): (1)

f. Methylprednisolone (Solu-Medrol): (1)

g. Prednisolone (Prelone): (1)

h. Prednisone: (1)

i. Triamcinolone (Acetocot, Amcort, Aristocort, Kenacort): (1)

j. Other *(specify):* (1)

_____
specify

k. Other *(specify):* (1)

_____
specify

49. Since the date in item 8, has the patient taken any cardiovascular/ antihypertensive medications:

Yes (1) No (2)

50.

(If yes or unsure, check all that apply):

a. Class III antiarrhythmic agent (Amiodarone [Pacerone]): (1)

b. Dihydropyridine calcium channel blocker (Amlodipine besylate [Norvasc], Felodipine [Plendil], Nifedipine [Adalat, Procardia]): (1)

c. Beta1-adrenergic blocker (Atenolol [Tenormin], Metoprolol [Lopressor]: (1)

d. Non-selective beta blocker (Caryedilol [Coreg], Propranolol [Inderal], Timolol maleate [Blocadren]): (1)

e. Angiotensin-converting-enzyme inhibitors (Benazepril [Lotensin], Captopril [Capoten], Enalapril [Vasotec], Lisinopril [Prinivil, Zestril], Ramipril [Altace], Quinapril [Accupril]): (1)

f. Alpha-2 adrenergic agonist (Clonidine [Catapres]): (1)

g. Digoxin (Lanoxin): (1)

h. Diltiazem (Cardizem): (1)

i. Alpha-1 adrenergic blocker (Doxazosin [Cardura], Terazosin [Hytrin]): (1)

j. Furosemide (Lasix): (1)

k. Hydrochlorothiazide (Esidrix, HydroDIURIL): (1)

l. Hydrochlorothiazide + triamterene (Dyazide): (1)

m. Angiotensin II receptor antagonist (Losartan potassium [Cozaar], Valsartan [Diovan], Candesartan [Atacand]): (1)

n. Losartan potassium with hydrochlorothiazide (Hyzaar): (1)

o. Verapamil (Calan): (1)

p. Other *(specify):* (1)

_____
specify

q. Other *(specify):* (1)

_____
specify

50. Since the date in item 8, has the patient taken any estrogen, progestin, hormone replacement therapy, or selective estrogen receptor modulators :

Yes (1) No (2)

51.

(If yes or unsure, check all that apply):

a. Conjugated estrogen (Premarin/Prempro): (1)

b. Diethylstilbestrol and methyltestosterone (Tylosterone): (1)

c. Esterified estrogen (Estratab, Menest): (1)

d. Estradiol (Estrace): (1)

e. Ethinyl estradiol (Estinyl): (1)

f. Androgens (Fluoxymesterone [Android-F, Halotestin], Methyltestosterone [Android], Nandrolone [Deca-Durabolin, Hybolin Decanoate, Kabolin]): (1)

g. Progestins (Norethindrone [Micronor], Progesterone [Prometrium], Norgestrel [Ovrette], Levonorgestrel [Norplant], Medroxyprogesterone [Cycrin, Provera], Megestrol [Megace]): (1)

h. Combination oral contraceptives (Alesse, Demulen, Desogen, Estrostep, Genora, Intercon, Levlen, Levlite, Levora, Loestrin, Lo-Ovral, Necon, Nelova, Nordette, Norethin, Norinyl, Ortho Cyclen, Ortho-Novum, Ortho Tri-Cyclen, Ovral, Tri-Levlen, Triphasil, Trivora, Zovia): (1)

i. Synthetic anabolic steroids (Oxandrolone [Oxandrin], Oxymetholone [Anadrol]): (1)

j. Selective estrogen receptor modulator (Raloxifene [Evista], Tamoxifen [Nolvadex]): (1)

k. Other *(specify):* (1)

_____
specify

l. Other *(specify):* (1)

_____
specify

J. Relevant medication use

For items 50-58: *Have the patient use flashcard #9a to indicate the frequency of use and flashcard #9b to indicate the perceived benefit for gastroparesis symptoms for each medication he/she uses/used*

51. Since the date in item 8, has the patient taken any proton pump inhibitors, histamine H2 receptor antagonists or other similar medications:

Yes (1) No (2)

52.

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Antacids, *(specify):*	____	____
_____ specify		
b. Cimetidine (Tagamet):	____	____
c. Dexlansoprazole (Dexilant):	____	____
d. Esomeprazole (Nexium):	____	____
e. Famotidine (Pepcid):	____	____
f. Lansoprazole (Prevacid):	____	____
g. Nizatidine (Axid):	____	____
h. Omeprazole (Prilosec, Zegerid):	____	____
i. Pantoprazole (Protonix):	____	____
j. Rabeprazole (Aciphex):	____	____
k. Ranitidine (Zantac):	____	____
l. Other *(specify):*	____	____
_____ specify		
m. Other *(specify):*	____	____
_____ specify		

52. Since the date in item 8, has the patient taken any prokinetic medications:

Yes (1) No (2)

53. ____

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Azithromycin (Zithromax):	____	____
b. Bethanechol (Duvoid, Urecholine):	____	____
c. Clarithromycin (Biaxin):	____	____
d. Domperidone (Motilium):	____	____
e. Erythromycin:	____	____
f. Metoclopramide (Reglan):	____	____
g. Prucalopride (Resolor) (see also 55m):	____	____
h. Tegaserod (Zelnorm):	____	____
i. Cisapride (Propulcid):	____	____
j. Other *(specify):*	____	____
specify		
k. Other *(specify):*	____	____
specify		

53. Since the date in item 8, has the patient had Botox injected into the pylorus for his/her gastroparesis symptoms:

Yes (1) No (2)

54. ____

a. Perceived benefit *(use flashcard #9b):* ____ (0-5)

b. Number of weeks since last injection: ____ ____ (00-48)

54. Since the date in item 8, has the patient used any of the following medications:

Yes (1) No (2)

54. ____

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Prochlorperazine (Compazine):	____	____
b. Promethazine (Pentazine, Phenergan):	____	____
c. Trimethobenzamide (Benzacot, Stemetic, Tigan):	____	____
d. Meclizine (Antivert):	____	____
e. Serotonin (5-HT3) antagonists (Ondansetron [Zofran], Tropisetron [Navoban], Granisetron [Kytril Sancuso Patch], Palonosetron [Aloxi], Dolasetron [Anzemet]):	____	____
f. Neurokinin-1 receptor antagonists (Aprepitant [Emend]):	____	____
g. Tricyclic antidepressants (Amitriptyline [Elavil], Desipramine [Norpramin], Imipramine [Tofranil], Nortriptyline [Aventyl, Pamelor]):	____	____
h. Dronabinol (Marinol) *(see also 60e):*	____	____
i. Tetracylcic antidepressants (Mirtazapine [Remeron]):	____	____
j. Bupropion (Wellbutrin):	____	____
k. Selective Serotonin Reuptake Inhibitors (SSRI)[Citalopram (Celexa), Escitalopram (Lexapro), Fluoxetine (Prozac), Paroxetine (Paxil), Sertraline (Zoloft)]:	____	____
l. Venlafaxine (Effexor):	____	____
m. Anxiolytic (Buspirone [BuSpar]):	____	____
n. Chlordiazepoxide (Librax):	____	____

	Frequency (1-6)	Benefit (0-5)
o. Benzodiazepines (Lorazepam [Ativan], Alprazolam [Xanax], Diazepam [Valium], Oxazepam [Serax], Clonazepam [Klonopin], Temazepam [Restoril, Temaz], Flurazepam):	____	____
p. Meprobamate:	____	____
q. Quetiapine fumarate (Seroquel):	____	____
r. Dicyclomine (Bentyl):	____	____
s. Olanzapine (Zyprexa):	____	____
t. Tetrahydrocannabinol (Syndros) (see also 60g):	____	____
u. Other *(specify):*	____	____

_____
specify

v. Other *(specify):*	____	____

_____
specify

55. Since the date in item 8, has the patient used any of the following medications for constipation:

Yes (1) No (2)

56.

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Bisacodyl (Dulcolax):	____	____
b. Colchicine (Colcrys):	____	____
c. Docusate sodium (Colace):	____	____
d. Fiber supplements:	____	____
e. Lactulose:	____	
f. Linaclotide (Linzess):	____	____
g. Lubiprostone (Amitiza):	____	____
h. Methylnaltrexone (Relistor):	____	____
i. Misoprostol (Cytotec):	____	____
j. Naloxegol (Movantik):	____	____
k. Plecanatide (Trulance):	____	____
l. Polyethylene glycol (Miralax):	____	____
m. Prucalopride (Resolar):	____	____
n. Senna (Senokot):	____	____
o. Magnesium oxide:	____	____
p. Other *(specify):*	____	____

_____
specify

56. Since the date in item 8, has the patient taken any pain relieving, analgesics, non-steroidal anti-inflammatory, or aspirin containing medications (non-narcotic) either regular usage or as needed basis (prn):

Yes (1) No (2)

57.

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Acetaminophen (Tylenol):	____	____
b. Aspirin - 325 mg:	____	____
c. Celecoxib (Celebrex):	____	____
d. Ibuprofen (Advil, Motrin):	____	____
e. Indomethacin (Indocin):	____	____
f. Naproxen (Aleve, Naprosyn):	____	____
g. Ketorolac (Toradol):	____	____
h. Other *(specify):*	____	____

_____
specify

i. Other *(specify):*	____	____

_____
specify

j. Other *(specify):*	____	____

_____
specify

57. Since the date in item 8, has the patient taken any narcotic pain medications:

Yes (1) No (2)

59.

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Acetaminophen (30 mg)/ codeine phosphate (Tylenol #3):	____	____
b. Acetaminophen (60 mg)/ codeine phosphate (Tylenol #4):	____	____
c. Acetaminophen/hydrocodone bitartrate (Lortab, Norco, Vicodin):	____	____
d. Acetaminophen/oxycodone hydrochloride (Percocet, Tylox):	____	____
e. Aspirin/oxycodone hydrochloride (Percodan):	____	____
f. Buprenorphine (Butrans patch):	____	____
g. Butalbital/acetaminophen/ caffeine (Esgic - Plus):	____	____
h. Fentanyl transdermal (Duragesic patch):	____	____
i. Fentanyl oral (Abstral, Actiq, Fentora):	____	____
j. Hydromorphone hydrochloride (Dilaudid):	____	____
k. Oxycodone hydrochloride (OxyContin):	____	____
l. Methadone hydrochloride:	____	____
m. Morphine sulfate:	____	____
n. Pentazocine (Talacen):	____	____
o. Tapentadol (Nucynta):	____	____
p. Tramadol HCl (Ultram/ Ultracet):	____	____
q. Other *(specify):*	____	____

_____
specify

Note: Participants should not be taking narcotic medications more than 3 days per week.

58. Is the patient taking the narcotic pain medication for *(check all that apply)*

a. Pain related to gastroparesis symptoms, including abdominal pain:	(1)
b. Headache pain:	(1)
c. Leg pain:	(1)
d. Back pain:	(1)
e. Other pain *(specify):*	(1)

_____
specify

59. Since the date in item 8, has the patient taken any of the following neuropathic pain medications:

Yes (1) No (2)

60.

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Duloxetine (Cymbalta):	____	____
b. Gabapentin (Neurontin):	____	____
c. Pregabalin (Lyrica):	____	____
d. Divalproex sodium (Depakote):	____	____
e. Topiramate (Topamax):	____	____
f. Other *(specify):*	____	____

_____
specify

K. Alternative therapies

For item 60: *Have the patient use flashcard #9a to indicate the frequency of use and flashcard #9b to indicate perceived benefit for gastroparesis symptoms for each medication he/she uses/used*

60. Since the date in item 8, has the patient used alternative medicine or complementary medicine products or procedures for treatment of his/her symptoms related to gastroparesis *(e.g., bloating, nausea, vomiting, abdominal pain):*

Yes (1) No (2)

61.

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Probiotic #1 *(specify):* _____ specify	____	____
b. Probiotic #2 *(specify):* _____ specify	____	____
c. Herbal supplement #1 *(specify):* _____ specify	____	____
d. Herbal supplement #2 *(specify):* _____ specify	____	____
e. Herbal supplement #3 *(specify):* _____ specify	____	____
f. Acupuncture:	____	____
g. Acupressure bands/bracelets:	____	____
h. Reflexology:	____	____
i. Hypnotherapy:	____	____
j. Therapeutic Massage:	____	____
k. Ginger:	____	____
l. Iberogast:	____	____
m. Other *(specify):* _____ specify	____	____

61. Since the date in item 8, has the patient used a cannabis product such as marijuana, THC (tetrahydrocannabinol), CBD (cannabidiol):

Yes (1) No (2)

63.

(If yes, answer all that apply using flashcards #9a and 9b):

	Frequency (1-6)	Benefit (0-5)
a. Marijuana (medical use):	____	____
b. Marijuana (non-medical/ recreational use):	____	____
c. THC:	____	____
d. CBD:	____	____
e. Marinol (Dronabinol) (see also 53h):	____	____
f. Nabilone (Cesamet):	____	____
g. Tetrahydrocannabinol (Syndros) (see also 53t):	____	____

62. For which reason(s) do you use these cannabis products: *(check all that apply)*

a. Recreational: (1)
b. Reduce nausea or vomiting: (1)
c. Reduce abdominal pain: (1)
d. Improve appetite: (1)
e. Other *(specify):* (1)

_____ specify

L. Administrative information

63. Study Physician PIN: ___ ___ ___

64. Study Physician signature:

_____

65. Clinical Coordinator PIN: ___ ___ ___

66. Clinical Coordinator signature:

_____

67. Date form reviewed:

___ ___ – ___ ___ – ___ ___
day mon year

Flash Card #9a	Which BEST DESCRIBES the FREQUENCY of use for the medication you took or are taking?
1	Used only one or two times since the date in item 8
2	Less than once per week
3	About once a week
4	Several times a week
5	About once per day
6	More than once per day

Flash Card #9b	Which BEST DESCRIBES the BENEFIT you received from the medication you took or are taking for your gastroparesis symptoms?
0	Not taking for gastroparesis symptoms
1	No or minimal benefit for gastroparesis symptoms
2	Better
3	Much better
4	Worse
5	Much worse